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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/040,161	03/17/1998	PAUL L. KORNBLITH	2509-980383	1498

7590 06/03/2004

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EXAMINER

GITOMER, RALPH J

ART UNIT PAPER NUMBER

1651

DATE MAILED: 06/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/040,161	KORNBLITH, PAUL L.	
	Examiner	Art Unit	
	Ralph Gitomer	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

The Remarks, IDS and Terminal Disclaimer received 2/6/04 have been entered and claims 13-20 are currently pending in this application. Priority is granted to 7/12/96.

Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. The feature of the size of the particulates is critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

On page 5 lines 15-16 of the present specification, "Preferably but not necessarily, the tumor particulates each measure 1 mm³." It would appear the claimed invention would not work unless the particulates were of a certain size and the specification teaches only this one size.

Claims 13-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for particles of a specific size, does not reasonably provide enablement for particles of any size. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

In claim 13 and all occurrences, the terms "cohesive multicellular particulates" lack enablement as it would require one of ordinary skill in this art undue experimentation to determine which size would work in the instant invention.

"Cohesive multicellular particulates" reads on an entire organ to two cells, neither of which are likely to work in the claimed invention. The addition to the claims of "having smooth cut edges" does not in any fashion distinguish the size of the particulates. And referring to minced tumor tissue, although indefinite regarding size, refers to very small samples.

Note this examiner was employed in a pathology lab where most of the samples he received were severed heads, either complete or portions thereof. Virtually all of the samples had at least one smooth cut edge at the neck where the specimen was prepared and most of the samples had some region of minced tissue, generally where an injury occurred such as a bullet exit wound. Most of the heads weighed 10-12 pounds, were cohesive multicellular particulates, had smooth cut edges and had minced tissue. And possibly some of the heads had tumor tissue which would then read on the presently claimed samples directly.

The entire scope of the claims has not been enabled because:

1. Quantity of experimentation necessary would be undue because of the large number of sizes claimed.
2. Amount of direction or guidance presented is insufficient to predict which sizes encompassed by the claims would work.
3. Presence of working examples are only for a single size and extension to other sizes has not been specifically taught or suggested.
4. The nature of the invention is complex and unpredictable.

5. State of the prior art indicates that most sizes are not effective for the claimed functions.

6. Level of predictability of the art is very unpredictable.

7. Breadth of the claims encompasses an innumerable number of sizes.

8. The level of one of ordinary skill in this art is variable.

In re Wands, 858 F.2d 731, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)

Claims 13-20 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 13, "cohesive multicellular particulates" is not understood as so what the specimen is separated into. Note the expression reads on no separating to forming two cell particulates.

Applicant argues that the sample size is not a critical feature and the sample would have to be of an appropriate size to culture. The purpose of culturing the cells is to assess a biopsy sample to avoid gross surgical intervention. The size limitations are readily deduced according to the teachings of the specification. No experimentation is required to practice the invention because a sample size is specified in the disclosure.

It is the examiner's position that in view of the prosecution of issued patent 5,728,541 for which a Terminal Disclaimer has been filed in the present application, the size of the sample is critical and this single feature is the sole difference between the claims in the applications.

The claims have no limitations directed to the size of the cohesive multicellular particulates and many sized samples can be cultured. When culturing environmental samples, for example, huge samples are routinely employed for culturing. The purpose of culturing the cells is unrelated to the size of the sample which is cultured.

Regarding the single size of the sample disclosed in the specification which may be cultured, Applicant is reminded that the invention is the subject matter defined by the claims, and the limitations of the specification are not read into the claims where no express statement of that limitation is included in the claims, see *In re Priest*, 199 USPQ 11.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

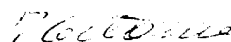
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ralph Gitomer whose telephone number is (571) 272-0916. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Ralph Gitomer
Primary Examiner
Art Unit 1651

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